

### AMENDMENTS TO THE CLAIMS

Please amend the claims so that they read as follows.

Claim 1 (Original): An intraorally rapidly disintegrable tablet which comprises

(a) fine granules comprising prepared by granulating a mixture of  
a water-soluble pharmacologically active ingredient and an adsorbent; selected from  
the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate,  
silicon dioxide and magnesium metasilicate aluminate,

(b) D-mannitol; and

(c) a disintegrator, wherein the water-soluble pharmacologically active ingredient and the  
adsorbent are contained in the fine granules.

Claim 2 (Canceled)

Claim 3 (Currently Amended): The intraorally rapidly disintegrable tablet as claimed in Claim 1, wherein the disintegrator is comprises at least one member selected from the group consisting of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose.

Claim 4 (Currently Amended): The intraorally rapidly disintegrable tablet as claimed in Claim 1, wherein the whole or a part of the D-mannitol is a primary particle and the specific surface area of the primary particle is  $1.0 \text{ m}^2/\text{g}$  or less and the average particle size of the primary particles is in the range of 10 to 300  $\mu\text{m}$ .

Claim 5 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 1, wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more.

Claim 6 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 1, wherein the water-soluble pharmacologically active ingredient is pravastatin sodium.

Claim 7 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 1, further containing a lubricant.

Claim 8 (Original): The intraorally rapidly disintegrable tablet as claimed in Claim 7, wherein the lubricant is contained only on the surface of the tablet.

Claim 9 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 7, wherein the lubricant is at least one member selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate, sucrose fatty acid ester and talc.

Claim 10 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 1, further containing at least one member selected from the group consisting of flavoring agents, sweeteners, perfumes, coloring agents, stabilizers, fluidizing agents, anti-oxidants and co-solubilizers.

Claim 11 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 1, wherein the compounding ratio of the water-soluble pharmacologically active ingredient to the adsorbent in the fine granules is 1:10 to 10:1.

Claim 12 (Currently Amended): The intraorally rapidly disintegrable tablet as claimed in Claim 1, wherein the ~~compounding ratio~~ amount of the fine granules in the tablet is 1 to 50% by weight.

Claim 13 (Currently Amended): The intraorally rapidly disintegrable tablet as claimed in Claim 1, wherein the ~~compounding ratio~~ amount of the D-mannitol in the tablet is 20 to 99% by weight.

Claim 14 (Currently Amended): The intraorally rapidly disintegrable tablet as claimed in Claim 1, wherein the ~~compounding ratio~~ amount of the disintegrator in the tablet is 0.5 to 30% by weight.

Claim 15 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claims 1, wherein the hardness of the tablet is 20N or higher.

Claim 16 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claims 1, wherein the disintegration time in oral cavity is 30 seconds or less.

Claim 17 (Currently Amended): A process for producing an intraorally rapidly disintegrable tablet which comprises ~~mixing fine granules prepared by~~ granulating a mixture of a water-soluble pharmacologically active ingredient and an adsorbent, selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate to prepare fine granules, mixing the fine granules, D-mannitol and a disintegrator to prepare a material for compression molding, and subjecting the material to compression molding.

Claim 18 (Canceled)

Claim 19 (Previously Presented): The process as claimed in Claim 17, wherein the disintegrator is at least one member selected from the group consisting of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose.

Claim 20 (Currently Amended): The process as claimed in Claim 17, wherein the whole or a part of the D-mannitol is a primary particle and the specific surface area of the primary particle is  $1.0 \text{ m}^2/\text{g}$  or less and the average particle size of the primary particles is in the range of 10 to 300  $\mu\text{m}$ .

Claim 21 (Previously Presented): The process as claimed in Claim 17, wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more.

Claim 22 (Previously Presented): The process as claimed in Claim 17, wherein the water-soluble pharmacologically active ingredient is pravastatin sodium.

Claim 23 (Previously Presented): The process as claimed in Claim 17, wherein the material for compression molding contains a lubricant.

Claim 24 (Currently Amended): The process as claimed in Claim 17, wherein the compression molding is carried out using a compression molding machine in which a lubricant is previously applied on the surface of the punch and ~~the~~ die.

Claim 25 (Previously Presented): The process as claimed in Claim 23, wherein the lubricant is at least one member selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate, sucrose fatty acid ester and talc.

Claim 26 (Previously Presented): The process as claimed in Claim 17, wherein the material for compression molding contains at least one member selected from the group consisting of flavoring agents, sweeteners, perfumes, coloring agents, stabilizers, fluidizing agents, anti-oxidants and co-solubilizers.

Claim 27 (Previously Presented): The process as claimed in Claim 17, wherein the compounding ratio of the water-soluble pharmacologically active ingredient to the adsorbent in the fine granules is 1:10 to 10:1.

Claim 28 (Currently Amended): The process as claimed in Claim 17, wherein the ~~compounding ratio~~ amount of the fine granules in the tablet is 1 to 50% by weight.

Claim 29 (Currently Amended): The process as claimed in Claim 17, wherein the ~~compounding ratio~~ amount of the D-mannitol in the tablet is 20 to 99% by weight.

Claim 30 (Currently Amended): The process as claimed in Claim 17, wherein the ~~compounding ratio~~ amount of the disintegrator in the tablet is 0.5 to 30% by weight.

Claim 31 (Currently Amended): An intraorally rapidly disintegrable tablet which comprises  
(a) fine granules comprising:  
~~is produced by mixing fine granules prepared by granulating a mixture of~~ a water-soluble  
pharmacologically active ingredient and an adsorbent selected from the group consisting of calcium  
silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium  
metasilicate aluminate;  
(b) D-mannitol; and  
(c) a disintegrator, to prepare a material for compression molding wherein the water-soluble  
pharmacologically active ingredient and the adsorbent are contained in the fine granules, and  
wherein the tablet is subjected to a compression molding tablet.

Claim 32 (Canceled)

Claim 33 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 31, wherein the disintegrator is at least one member selected from the group consisting of croscovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose.

Claim 34 (Currently Amended): The intraorally rapidly disintegrable tablet as claimed in Claim 31, wherein whole or a part of the D-mannitol is a primary particles and the specific surface area of the primary particle is  $1.0 \text{ m}^2/\text{g}$  or less and the average particle size of the primary particles is in the range of 10 to 300  $\mu\text{m}$ .

Claim 35 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 31, wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more.

Claim 36 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 31, wherein the water-soluble pharmacologically active ingredient is pravastatin sodium.

Claim 37 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 31, wherein the material for compression molding contains a lubricant.

Claim 38 (Currently Amended): The intraorally rapidly disintegrable tablet as claimed in Claim 31, wherein the compression molding is carried out using a compression molding machine in which a lubricant is previously applied on the surface of the punch and ~~the~~ die.

Claim 39 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 37, wherein the lubricant is at least one member selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate, sucrose fatty acid ester and talc.

Claim 40 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 31, wherein the material for compression molding contains at least one member selected from the group consisting of flavoring agents, sweeteners, perfumes, coloring agents, stabilizers, fluidizing agents, anti-oxidants and co-solubilizers.

Claim 41 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 31, wherein the compounding ratio of the water-soluble pharmacologically active ingredient to the adsorbent in the fine granules is 1:10 to 10:1.

Claim 42 (Currently Amended): The intraorally rapidly disintegrable tablet as claimed in Claim 31, wherein the ~~compounding ratio~~ amount of the fine granules in the tablet is 1 to 50% by weight.

Claim 43 (Currently Amended): The intraorally rapidly disintegrable tablet as claimed in Claim 31, wherein the ~~compounding ratio~~ amount of the D-mannitol in the tablet is 20 to 99% by weight.

Claim 44 (Currently Amended): The intraorally rapidly disintegrable tablet as claimed in Claim 31, wherein the ~~compounding ratio~~ amount of the disintegrator in the tablet is 0.5 to 30% by weight.

Claim 45 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 31, wherein the hardness of the tablet is 20N or higher.

Claim 46 (Currently Amended): The intraorally rapidly disintegrable tablet as claimed in Claim 31, wherein the disintegration time in the oral cavity is 30 seconds or less.

Claim 47 (Currently Amended): A process for producing an intraorally rapidly disintegrable tablet which comprises granulating a mixture of

- (a) a water-soluble pharmacologically active ingredient;
- (b) an adsorbent; selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate;
- (c) D-mannitol; and
- (d) a disintegrator to prepare a material for compression molding, and

subjecting the material to compression molding.

Claim 48 (Canceled):

Claim 49 (Previously Presented): The process as claimed in Claim 47, wherein the disintegrator is at least one member selected from the group consisting of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose.

Claim 50 (Currently Amended): The process as claimed in Claim 47, wherein whole or a part of the D-mannitol is a primary particle and the specific surface area of the primary particle is  $1.0 \text{ m}^2/\text{g}$  or less and the average particle size of the primary particles is in the range of 10 to 300  $\mu\text{m}$ .

Claim 51 (Previously Presented): The process as claimed in Claim 47, wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more.

Claim 52 (Previously Presented): The process as claimed in Claim 47, wherein the water-soluble pharmacologically active ingredient is pravastatin sodium.

Claim 53 (Previously Presented): The process as claimed in Claim 47, wherein the material for compression molding contains a lubricant.

Claim 54 (Currently Amended): The process as claimed in Claim 47, wherein the compression molding is carried out using a compression molding machine in which a lubricant is previously applied on the surface of the punch and ~~the~~ die.

Claim 55 (Previously Presented): The process as claimed in Claim 53, wherein the lubricant is at least one member selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate, sucrose fatty acid ester and talc.



Claim 56 (Previously Presented): The process as claimed in Claim 47, wherein the compression molding material contains at least one member selected from the group consisting of flavoring agents, sweeteners, perfumes, coloring agents, stabilizers, fluidizing agents, anti-oxidants and co-solubilizers.

Claim 57 (Previously Presented): The process as claimed in Claim 47, wherein the compounding ratio of the water-soluble pharmacologically active ingredient to the adsorbent in the compression molding material is 1:10 to 10:1.

Claim 58 (Currently Amended): The process as claimed in Claim 47, wherein the ~~compounding ratio~~ amount of the water-soluble pharmacologically active ingredient and the adsorbent in the tablet is 1 to 50% by weight.

Claim 59 (Currently Amended): The process as claimed in Claim 47, wherein the ~~compounding ratio~~ amount of the D-mannitol in the tablet is 20 to 99% by weight.

Claim 60 (Currently Amended): The process as claimed in Claim 47, wherein the ~~compounding ratio~~ amount of the disintegrator in the tablet is 0.5 to 30% by weight.

Claim 61 (Currently Amended): An intraorally rapidly disintegrable tablet which comprises fine granules comprising:

- (a) a water-soluble pharmacologically active ingredient;
  - (b) an adsorbent, selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate;
  - (c) D-mannitol; and
  - (d) a disintegrator,
- wherein the water-soluble pharmacologically active ingredient, the adsorbent, the D-mannitol and the disintegrator are contained in fine granules, and wherein the tablet is a compression molding tablet.

Claim 62 (Canceled)

Claim 63 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 61, wherein the disintegrator is at least one member selected from the group consisting of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose.

Claim 64 (Currently Amended): The intraorally rapidly disintegrable tablet as claimed in Claim 61, wherein whole or a part of the D-mannitol is a primary particle and the specific surface area of the primary particle is  $1.0 \text{ m}^2/\text{g}$  or less and the average particle size of the primary particles is in the range of 10 to 300  $\mu\text{m}$ .

Claim 65 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 61, wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more.

Claim 66 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 61, wherein the water-soluble pharmacologically active ingredient is pravastatin sodium.

Claim 67 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 61, containing a lubricant.

Claim 68 (Original): The intraorally rapidly disintegrable tablet as claimed in Claim 67, wherein the lubricant is contained only on the surface of the tablet.

Claim 69 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 67, wherein the lubricant is at least one member selected from the group consisting of

magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate, sucrose fatty acid ester and talc.

Claim 70 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 61, further containing at least one member selected from the group consisting of flavoring agents, sweeteners, perfumes, coloring agents, stabilizers, fluidizing agents, anti-oxidants and co-solubilizers.

Claim 71 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 61, wherein the compounding ratio of the water-soluble pharmacologically active ingredient to the adsorbent is 1:10 to 10:1.

Claim 72 (Currently Amended): The intraorally rapidly disintegrable tablet as claimed in Claim 61, wherein the ~~compounding ratio~~ amount of the water-soluble pharmacologically active ingredient and the adsorbent in the tablet is 1 to 50% by weight.

Claim 73 (Currently Amended): The intraorally rapidly disintegrable tablet as claimed in Claim 61, wherein the ~~compounding ratio~~ amount of the D-mannitol in the tablet is 20 to 99% by weight.

Claim 74 (Currently Amended): The intraorally rapidly disintegrable tablet as claimed in Claim 61, wherein the ~~compounding ratio~~ amount of the disintegrator in the tablet is 0.5 to 30% by weight.

Claim 75 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 61, wherein the hardness of the tablet is 20N or higher.

Claim 76 (Previously Presented): The intraorally rapidly disintegrable tablet as claimed in Claim 61, wherein the disintegration time in the oral cavity is 30 seconds or less.